



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/367,361	08/11/1999	BURKHARD SCHLUTERMANN	4-21233/A	4260

1095 7590 07/29/2003

THOMAS HOXIE  
NOVARTIS, CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

EXAMINER

SPEAR, JAMES M

ART UNIT	PAPER NUMBER
----------	--------------

1615

DATE MAILED: 07/29/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS  
UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
www.uspto.gov

MAILED  
JUL 29 2003  
GROUP 2 1600

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Paper No. 19

Application Number: 09/367,361

Filing Date: 08/11/1999

Appellant(s): BURKHARD SCHLUTERMANN

---

JOHN D. THALLEMER

For Appellant

Art Unit: 1615

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed MAY 08, 2003.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

Art Unit: 1615

**(6) Issues**

The appellant's statement of the issues in the brief is correct.

**(7) Grouping of Claims**

The rejection of claims 16-20 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

✓ 5,472,714	BOURQUIN	12-1995
-------------	----------	---------

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bourquin US 5,472,714.

The Bourquin reference teaches color-stable tablets comprising: (1.) A therapeutic drug oxcarbazepine tablet core prepared by a compacting method. Dry granulation is used

Art Unit: 1615

followed by compressing the active agent with the adjuncts to form larger objects such as coarse lumps, followed by comminuting these by grinding and compressing the grinding stock to tablet cores. See column 2, lines 14-27, column 2, line 52 to column 3, line 15. and (2.) a hydrophilic, permeable outer layer containing white pigments in combination with iron (II) oxide pigments. See Abstract.

The difference between the claimed invention and the teachings of the Bourquin reference is that appellant includes the particle size distribution for the oxcarbazepine which is described in the specification as preferred, not as critical nor established as critical to the composition, affording an unexpected property. The reference uses the same drug after mechanically grinding to fine particles, but fails to mention the particle size distribution. All of the examples in the specification use oxcarbazepine as the active drug in association with other excipients to form a mixture, which is ground in conventional manner, just as the reference process does. Appellant's examples fail to disclose the particle size distribution and establish the unexpected property of the tablets provided by the claimed particle size distribution. It is generally accepted in the art that drugs in the form of particles are easily dispersed or dissolved in the system for its quick action. The mere fact that appellant discloses to use a formulation of oxcarbazepine comprising oxcarbazepine having preferable median particle sizes of the finely ground form does not support a conclusion of criticality of the particle size distribution. (Page 1, lines 19-22). *In re Courtright*, 153 USPQ 735, 740

Art Unit: 1615

(CCPA 1967). *In re Shepard*, 50 CCPA 1439, 319 F. 2d 194, 138 USPQ 148, and cases cited therein. Even if appellant established an unexpected observation that the drug particles of the claimed size distribution are readily dissolved in the system such an observation is not unexpected, since it is generally accepted in the art that drugs should be in finely ground state to be immediately available to the system at the point of desired delivery. The composition of the outer layer in appellant's claimed tablets is the same as the composition of the outer layers of the reference tablets, whether one calls the outer coating as one-layer or two-layer. It is well known in the art that drugs in the form of finite particles are easily dispersed, dissolved and absorbed into the system. Appellant uses the same conventional grinding process as the reference. The particle size distribution in the reference tablet is expected to be essentially identical with or similar to the appellant's claimed size distribution.

It would have been obvious to one of ordinary skill in the art to follow the teachings of Bourquin and formulate the same tablet with a core of oxcarbazepine and other excipients using conventional coating techniques for an outer layer comprising white pigments and iron oxide pigments including a non-critical particle size distribution for the core drug within the range of applicant's. The motivation being suggested by the general state of the art teaching the same core drug oxcarbazepine with excipients being subjected to some degree of grinding to reduce the drug into fine particles, mechanically compacted into tablets and coated to impart protective and aesthetic properties. The finite particles having particle size

Art Unit: 1615

distributions as cited above would provide for optimum absorption and bioavailability of the oxcarbazepine.

**(11) Response to Argument**

Appellants state that in contrast to the teachings of Bourquin they achieve color and storage stability in oxcarbazepine tablets using a single coating on the tablet core. "Appellant unexpectedly determined that color stability is achieved using only a single coating provided that the oxcarbazepine has a fine particle size and a narrow particle size distribution."

The particle size is not considered a patentable distinction as explained above. The presence or absence of an inert coating when coating thickness has not been shown by to be critical is not considered a distinguishing feature.

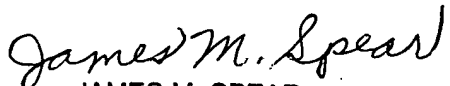
CONFeree:

  
THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

CONFeree:



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1000

  
JAMES M. SPEAR  
PRIMARY EXAMINER  
ART UNIT 1615

JAMES M. SPEAR July 17, 2003



**UNITED STATES PATENT AND TRADEMARK OFFICE**

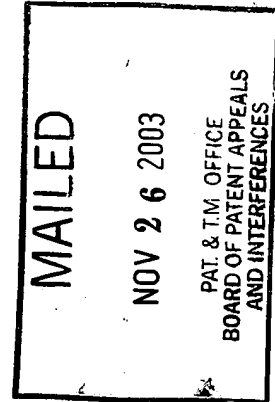
UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND  
DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE  
WASHINGTON, D.C. 20231  
[www.uspto.gov](http://www.uspto.gov)

THOMAS HOXIE  
NOVARTIS  
CORPORATE INTELLECTUAL PROPERTY  
ONE HEALTH PLAZA 430/2  
EAST HANOVER, NJ 07936-1080

Paper No: 20  
Appeal No: 2004-0377  
Appellant: SCHLUTERMANN, BURKHARD  
Application: 09/367,361

**Board of Patent Appeals and Interferences  
Docketing Notice**

Application 09/367,361 was received from the Technology Center at the Board on November 20, 2003 and has been assigned Appeal No: 2004-0377.



A review of the file indicates that the following documents have been filed by appellant:

Appeal Brief filed on: May 8, 2003  
Reply Brief filed on: None  
Request for Hearing filed on: None

In all future communications regarding this appeal, please include both the application number and the appeal number.

The mailing address for the Board is:

**BOARD OF PATENT APPEALS AND INTERFERENCES  
UNITED STATES PATENT AND TRADEMARK OFFICE  
P.O. BOX 1450  
ALEXANDRIA, VIRGINIA 22313-1450**

The facsimile number of the Board is 703-308-7952. Because of the heightened security in the Washington D.C. area, facsimile communications are recommended. Telephone inquiries can be made by calling 703-308-9797 and should be directed to a Program and Resource Administrator.

By order of the Board of Patent Appeals and Interferences